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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,094	06/30/2003	Ravi F. Saraf	20140-00288-US1	5220
30678 7590 07/13/2007 CONNOLLY BOVE LODGE & HUTZ LLP 1875 EYE STREET, N.W. SUITE 1100 WASHINGTON, DC 20036			EXAMINER FREDMAN, JEFFREY NORMAN	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 07/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/608,094

Applicant(s)

SARAF, RAVI F.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 160-163 and 165-200 is/are pending in the application.
- 4a) Of the above claim(s) 167-200 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 160-163, 165 and 166 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 13, 2007 has been entered. information disclosure statement filed December 7, 2006 complies with the IDS rules and the quantum dot reference is considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The rejection of claims 160-163 and 165 under 35 U.S.C. 102(e) as being anticipated by Heller et al (U.S. Patent 6,017,696) are withdrawn in view of the amendment. Heller does not teach anything regarding "recrystallization".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of claim 166 under 35 U.S.C. 103(a) as being unpatentable over Heller et al (U.S. Patent 6,017,696) is also withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112 – Second Paragraph

6. Claims 160-163, 165 and 166 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by the phrase "prohibits recrystallization of said denatured segment". To use the language of the Federal Circuit, this phrase is insolubly ambiguous. While it is expressly used in the specification (see page 8, line 1, and page 9, line 6, in particular), the meaning of "recrystallization" is indefinite with regard to these claims. Based upon the usage at page 9, line 6, it appears that recrystallization is an alternative which differs from renaturation, but which is used in reference to nucleic acids. Thus, recrystallization is not simply renaturation of the nucleic acid but is some other process. The specification does not define or explain what is meant by "recrystallization". While there is no doubt that nucleic acids can be "crystallized" (see Osica et al (Molecular Biology Reports (1976) 3:73-79), that type of crystallization is used for X-ray diffraction or NMR studies, requires very large amounts

of nucleic acid in solution and does not involve denatured segments. Therefore, the phrase "prohibits recrystallization of the denatured segment" is indefinite.

Claim Rejections - 35 USC § 112 - Enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 160-163, 165 and 166 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to a method of storing information using electrical current on DNA arrays where chemical insertion compounds "prohibits recrystallization of the denatured segment". The invention is is a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims are very broad with regard to the types of insertion compounds which can be used. Essentially any chemical which would react with an "amide group" and which would "prohibit recrystallization" would fall within the scope of the claim as an "insertion compound".

Quantity of Experimentation

The quantity of experimentation in this area is large since there is significant variability in the functionality of different compounds. Particularly difficult is determining whether the compound would function to "prohibits recrystallization of the denatured segment". DNA crystallization, as discussed by Osica et al (*Molecular Biology Reports* (1976) 3:73-79), required particular conditions that are fairly extreme. That is, DNA crystallization was performed at 4 C, with particular salt concentrations and very large DNA concentrations of 2-4.5 mg/ml (see page 75, first paragraph). Thus, it appears that it would require a large amount of unpredictable experimentation to identify compounds which would prohibit recrystallization of the denatured segment.

The unpredictability of the art and the state of the prior art

It is highly unpredictable how to prohibit DNA recrystallization using an insertion compound bound to an amide group. Monar et al (J. Polym. Sci. B : Polym. Phys 35 :1843-1854 (1997) teaches recrystallization of DNA, but Monar indicates that these crystals are formed in one of three ways (see page 1848, column 1). Monar notes that either rapid dehydration of under shear conditions or concentrated solutions of small homogenous DNA fragments or supersaturation of complicated mixtures with cations or dehydration are used to form DNA crystals. Monar has no discussion on how to prevent recrystallization using insertion molecules. In fact, no prior art could be identified which discussed DNA crystallization in a context similar to the electrical microarray of Heller or Applicant. It is entirely unpredictable how recrystallization would occur in these systems, when none of the standard techniques of crystallization of DNA are being used in the specification. The specification never discusses the use of saturated or supersaturated solutions or rapid dehydration to form the DNA recrystallization products. It is entirely unpredictable how to prevent recrystallization when there is little likelihood that crystals will form.

Working Examples

The specification does not appear to have any working examples.

Guidance in the Specification.

The specification expressly states the use of insertion compounds to prohibit recrystallization of the denatured segment. However, the specification equally clearly differentiates between renaturation and recrystallization at page 9, line 6. The specification never defines the term "recrystallization". The specification never tells the ordinary practitioner what is meant by "prohibiting recrystallization" or what phase of nucleic acid is meant by this phrase. Further, the specification fails to teach how

reaction with an "amide" group will "prohibit recrystallization". Thus, the specification fails to teach sufficient information to permit the ordinary practitioner to practice the invention.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the level of unpredictability and the teaching support a conclusion that "prohibiting recrystallization of said denatured segment" is not enabled by the specification. The specification provides one with no written description or guidance that leads one to a reliable method for "prohibiting recrystallization of said denatured segment". One of skill in the art cannot readily perform an assay in which a compound functions in "prohibiting recrystallization of said denatured segment". Thus given the claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define the unpredictable insertion compounds which would function to prohibit recrystallization, the lack of guidance provided in the specification, the absence of any working examples balanced only against the high skill level in the art, it is concluded that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

9. Applicant's arguments filed June 13, 2007 have been fully considered but they are not persuasive.

Applicant's arguments with regard to the applicability of the Heller reference to the claims as amended were found entirely persuasive. However, the newly added

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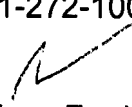
limitation, while not new matter due to express support in the specification, was rejected under both 112, first and second paragraphs for the reasons given above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jeffrey Fredman
Primary Examiner
Art Unit 1637

7/5/07